UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,988	01/29/2002	Zhihao Yang	83965HEC	6122

7590 11/05/2003

Paul A. Leipold
Patent Legal Staff
Eastman Kodak Company
343 State Street
Rochester, NY 14650-2201

EXAMINER	
CHAKRABARTI, ARUN K	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/059,988	Yang
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Oct 8, 2003* .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-14* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1-14* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [X] Other: *Detailed Action*

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 8, 2003 has been entered.

Specification

2. Claims 1-6 and 8-14 have been amended. No new claims have been added. Claims 1-14 are pending in this application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-14 are rejected under 35 U.S.C. 103 (a)over Gilmanshin et al. (U.S. Patent 6,263,286 B1) (July 17, 2001) in view of Cubicciotti (U.S. Patent 6,287,765 B1) (September 11, 2001) further in view of Schwartz et al. (U.S. Patent 6,221,592 B1) (April 24, 2001).

Gilmanshin et al teach a method for single molecule identification of a target DNA molecule in a random coil state (Abstract, Column 26, lines 45 to column 27, line 10 and Figures 8-9) comprising the following steps:

a) attaching an optically distinguishable material to a DNA sequence recognition unit (Column 25, lines 35-54);

b) hybridizing the DNA sequence recognition unit to the target DNA molecule in a random coil state to form a hybridized DNA complex in a random coil state (Column 19, lines 42-63);

c) stretching the hybridized DNA complex in a random coil state to form a hybridized DNA complex in a substantially linear configuration (Column 26, lines 45 to column 27, line 10 and Figures 8-9); and

d) detecting the optically distinguishable material in a sequential manner along the substantially linear hybridized DNA complex, thereby identifying the target DNA molecule (Examples 2-3 and Figure 9).

Gilmanshin et al teach a method wherein the optically distinguishable material comprises colored microparticles having different shapes (Column 25, line 18 to column 26, line 37 and figure 8).

Gilmanshin et al teach a method, wherein the colored microparticles comprise dye or nanocrystals (column 16, lines 38-50).

Gilmanshin et al teach a method, wherein the DNA sequence recognition unit comprises DNA or peptide nucleic acids (column 8, lines 36-62).

Gilmanshin et al teach a method, wherein the DNA sequence recognition units comprise any protein scaffold or synthetic molecular moiety capable of recognizing a specific DNA sequence (column 8, lines 36-62 and Column 17, lines 52-65).

Gilmanshin et al teach a method, wherein the stretching of the hybridized DNA complex in a random coil state to form a hybridized DNA complex in a substantially linear configuration is accomplished by using a mechanical means (Column 26, line 64 to Column 27, line 10).

Gilmanshin et al teach a method for single molecule identification of a target DNA molecule in a random coil state (Abstract, Column 26, lines 45 to column 27, line 10 and Figures 8-9) comprising the following steps:

a) stretching the hybridized DNA complex in a random coil state to form a hybridized DNA complex in a substantially linear configuration (Column 26, lines 45 to column 27, line 10 and Figures 8-9);

b) attaching an optically distinguishable material to a DNA sequence recognition unit (Column 25, lines 35-54);

c) hybridizing the DNA sequence recognition unit to the target DNA molecule in a substantially linear configuration to form a hybridized DNA complex in a substantially linear configuration (Column 19, lines 42-63); and

d) detecting the optically distinguishable material in a sequential manner along the substantially linear hybridized DNA complex, thereby identifying the target DNA molecule (Examples 2-3 and Figure 9).

Gilmanshin et al does not teach a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater.

Cubicciotti teaches a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater (Column 246, line 65 to Column 247, line 53).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater of Cubicciotti into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanshin et al., since Cubicciotti states, "For example, by varying the size, density and/or surface charge of the reporter conjugated to target molecules and nucleic acids comprising a random-sequence library, an affinity threshold or set point can be established to select an individual aptamer or group of aptamers with desired binding strength. The aptamer binding strength required to assemble two nanospheres (i.e., target-nanosphere and aptamer-nanosphere conjugates) and remain bound throughout selection, detection and isolation steps increases exponentially with particle diameter. Affinity set points spanning more than four orders of magnitude can be established using as reporters uniform latex nanospheres having particle diameters ranging from 10-300 nm (Column 247, lines 1-13). " By employing scientific reasoning, an ordinary artisan would have combined and substituted a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater of Cubicciotti into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanshin et al. in order to improve the analysis of a single nucleic acid molecule detection. An ordinary practitioner would have been motivated to combine and substitute a method of single molecule identification, wherein the optically distinguishable material has a size of about 0.05 micrometer or greater of Cubicciotti into the method for single

molecule identification of a target DNA molecule in a random coil state of Gilmanshin et al., in order to achieve the express advantages, as noted by Cubicciotti, of a novel invention by which varying the size, density and/or surface charge of the reporter conjugated to target molecules and nucleic acids comprising a random-sequence library, an affinity threshold or set point can be established to select an individual aptamer or group of aptamers with desired binding strength.

Gilmanshin et al. in view of Cubicciotti do not teach the method, wherein two or more different optically distinguishable DNA sequence recognition units are formed by attaching a unique, optically distinguishable material to each of the two or more DNA sequence recognition unit.

Schwartz et al. teaches the method, wherein two or more different optically distinguishable DNA sequence recognition units are formed by attaching a unique, optically distinguishable material to each of the two or more DNA sequence recognition unit (Abstract, Column 1, lines 13-25, Column 6, lines 51-59, Column 12, lines 33-44, and Column 32, lines 23-34).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein two or more different optically distinguishable DNA sequence recognition units are formed by attaching a unique, optically distinguishable material to each of the two or more DNA sequence recognition unit of Schwartz et al. into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanshin et al in view of Cubicciotti, since Schwartz et al. states, "The

present invention relates to methods for optically imaging a single labeled nucleotide or multiple labeled nucleotides on an individual double stranded nucleic acid molecule. The methods described herein can be utilized for the accurate, rapid, high throughput analysis of nucleic acid molecules at the genomic level and may, for example, include the detection of specific nucleotide sequences within a genome. (Column 6, lines 51-59) " By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein two or more different optically distinguishable DNA sequence recognition units are formed by attaching a unique, optically distinguishable material to each of the two or more DNA sequence recognition unit of Schwartz et al. into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanshin et al in view of Cubicciotti in order to improve the analysis of a single nucleic acid molecule detection. An ordinary practitioner would have been motivated to combine and substitute a method, wherein two or more different optically distinguishable DNA sequence recognition units are formed by attaching a unique, optically distinguishable material to each of the two or more DNA sequence recognition unit of Schwartz et al. into the method for single molecule identification of a target DNA molecule in a random coil state of Gilmanshin et al in view of Cubicciotti, in order to achieve the express advantages, as noted by Schwartz et al., of an invention which provides methods that can be utilized for the accurate, rapid, high throughput analysis of nucleic acid molecules at the genomic level and may, for example, include the detection of specific nucleotide sequences within a genome.

Response to Amendment

5. In response to amendment, previous 103(a) rejection has been withdrawn. However, a new 103(a) rejection has been included.

Response to Arguments

6. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner,

October 23, 2003

Gary Benzion

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600